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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/377,795	08/20/99	KARIN	M P-UD-3613

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HM22/0213

EXAMINER

SCHMIDT, M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/377,795

Applicant(s)

KARIN ET AL.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. Applicant's election without traverse of Group II, claims 11-17, in Paper No. 7, filed 11/28/00, is acknowledged.

Information Disclosure Statement

2. The information disclosure statement filed 11/22/99 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The references were not found with the application. Another copy of the IDS list of references is requested along with copies of the references.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 11-15 are indefinite for the language "substantially the same amino acid sequence." The specification as filed does not clearly define the metes and bounds of "substantially the same amino acid sequence" to teach what possible sequences are considered "substantially the same." The specification merely recites an example that 55% amino acid identity is "substantially the same." Therefore it is not clear whether this is considered the lower range of "substantial" identity so that any protein having about 55% amino acid identity is encompassed by the claimed invention.

5. Claims 11-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to amino acid sequences or nucleic acid sequences to an isolated IkappaB (IKK) subunit, IKK-gamma, or fragments thereof. The claims read on any sequence having "substantially the same" sequence as SEQ ID No. 2 or specified fragments thereof. In view of the indefiniteness of the language "substantially the same" the metes and bounds of the genus of possible sequences claimed is not clear. As written, the claims encompass possible sequences from species other than human.

The specification as filed only teaches the nucleic acid and amino acid sequence structures of an isolated human IkappaB (IKK) subunit, IKK-gamma. Neither the specification nor the art

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teach substitutions, additions or substitutions of the IKK-gamma subunit sequence which would be considered to provide a functional IKK-gamma sequence from any other organism (species).

Since neither the art nor the specification teach by way of example the sequence structure of related species of IkappaB (IKK) subunit, IKK-gamma, one skilled in the art does not have a representative number of species to be in possession of the broad scope of any potential IkappaB (IKK) subunit, IKK-gamma sequence claimed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamaoka et al. (*Cell*, Vol. 93, pp. 1231-1240, 6/26/98; see also attached copy of Genbank Accession Number AF069542 (DNA sequence) and Medline Accession Number 98319237 (Protein sequence))

Claims 11-17 are drawn to IKK-gamma nucleic acid molecules comprising a nucleotide sequence encoding substantially the same amino acid sequence as SEQ ID NO:2, having 55%

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amino acid identity with SEQ ID NO:2, comprising nucleotides 149-1408 of SEQ ID NO:1, comprising at least 9 consecutive nucleotides of SEQ ID NO:1, or an antisense comprising at least 9 consecutive nucleotides of SEQ ID NO:1.

Yamaoka et al. teach a nucleic acid sequence and amino acid sequence which would be considered by one of skill in the art to be substantially identical to the claimed SEQ ID Nos. 1 and 2. They further teach the structural and functional characteristics of the full-length cDNA which encodes a 48KD protein they call NEMO, which has the same functional and structural characteristics taught in the instant specification for the claimed sequences. Yamaoka et al. thus anticipate the claimed invention.

8. Claims 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (Genbank Accession Number AA402683, Nov. 9, 1997).

Claims 16-17 are drawn to nucleic acid molecules comprising at least 9 consecutive nucleotides of SEQ ID NO:1. Hillier et al. teach a nucleic acid molecule comprising at least 9 consecutive nucleotides of SEQ ID NO:1 and thus anticipate the claimed invention.

9. Claims 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al. (Genbank Accession Number AA387553).

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Claims 16-17 are drawn to nucleic acid molecules comprising at least 9 consecutive nucleotides of SEQ ID NO:1. Marra et al. teach a nucleic acid molecule comprising at least 9n consecutive nucleotides of SEQ ID NO:1 and thus anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, Katrina Turner, whose telephone number is (703) 305-3413.

M. M. Schmidt
February 11, 2001


REMY YUCEL, PH.D
PRIMARY EXAMINER